

REMARKS

Claims 1-12 and 14-15 are now pending.

The Applicants kindly thank the Examiner for the telephonic interview with Dr. Ronald Pero and the undersigned on November 30, 2005. The amendments to the claims presented herewith are particularly presented to distinguish the cited art - as discussed - in the interview.

A ► As proposed in the interview, claim 1 is now limited to a process for producing a specific resulting composition of water-soluble phytomedicinal compounds consisting essentially of -- only the recited steps. Accordingly, since Ishihara removes entities greater than 6kd *and* less than 3kd, *the instant claims now presented cannot encompass the process of Ishihara.*

B ► The second step of the claimed process requires specifically removing substantially all entities having a molecular weight greater than about 10kd from the extract to produce a composition of water-soluble phytomedicinal compounds resulting from the specific removal of substantially all entities having a molecular weight greater than about 10kd.

The Applicants, importantly, respectfully highlight to the Examiner that the process of the present invention is based upon the valuable but fundamental specific size exclusion; i.e., the removal of components that specifically over about 10kd, per se, in size, to result in a cognate composition.¹

¹ Large molecular weight entities that cause toxic side effects and/or function as inhibitor(s) of otherwise efficacious phytocompounds including metabolites are specifically removed to substantially eliminate all entities more than about 10,000 daltons in molecular weight. Particularly, resulting water-soluble

The claimed process, as a physical corollary, necessarily yields, i.e., literally produces a composition containing water-soluble compounds which range in size from 0 to about 10kd. It is this specific size fraction of water soluble components that exhibit improved nutraceutical properties including , but not limited to, bioavailability, efficacy, and reduced toxicity. *See, e.g.*, page 3, lines 20-25; page 4, lines 14-20; page 5, lines 15-21, page 6, line 28, *et seq.*; and Example II of the instant disclosure.

Rejections under 35 USC § 112

The Applicants herein respectfully amend claims 1 and 13, without prejudice, to remove the previously added language, “substantially complete”, that has caused the Examiner concern. The Applicants therefore respectfully request the Examiner to withdraw rejections under 35 USC § 112.

Rejections under 35 USC § 102

Ishihara

The process of Ishihara to produce compositions specifically excludes compounds within the compositions which have a molecular weight between about 0-3 kd AND over 6 kd. In other words, Ishihara teaches a method for isolating a specific composition of compounds, i.e., a precise composition of compounds between 3-6 kd. However, in sharp contrast, the Applicants specifically teach a method of producing a distinct composition of compounds between 0-10 kd, i.e., a distinct process *consisting essentially of two steps* which yields a distinct composition.

The Applicants’ particularly point out the claimed method herein cannot encompass the Ishihara, *et al.*, disclosure as a matter of law, because the fractionation limitation, i.e., specifically removing substantially all entities having a molecular weight greater than about 10kd from the extract to produce a composition of water-soluble phytomedicinal compounds resulting from the specific removal of substantially all entities having a molecular weight greater than about 10kd -- is not met.

compositions of the present invention are substantially devoid of molecular entities larger than about 10 kd (10,000 daltons Molecular Weight (MW)).

The Applicants respectfully submit that the English language is clear. A specific action is performed to produce (yield) a specific result. **The specific action:** removing substantially all entities having a molecular weight greater than about 10kd. **Result:** a composition specifically resulting from having removed substantially all entities having a specific molecular weight, i.e., greater than about 10kd.

Accordingly, the disclosure of Ishihara (the '862 patent), i.e., the process, is necessarily distinct from the subject matter of the claims presented herewith. The Applicants respectfully submit that the instant claims cannot be anticipated by the disclosure of Ishihara as a matter of law.

Lunder

Lunder particularly describes a process of obtaining catechin complexes from plant aqueous extracts. The extracts are concentrated via centrifugation and extracted with dichloromethane. The aqueous phase is mixed with purified sea sand to form a paste which is eluted with acetone to obtain catechin complexes in the acetone. However, Lunder performs no size fractionation. Accordingly, the disclosure of Lunder (the '000 patent) is necessarily distinct from the subject matter of the claims presented herewith. The Applicants respectfully submit that the instant claims cannot be anticipated by the disclosure of Lunder as a matter of law.

The Applicants respectfully request the Examiner to withdraw all rejections under 35 USC § 102.

Rejections under 35 USC § 103

The Applicants respectfully highlight the fact that, although the disclosures of both Ishihara, *et al.*, ('862 patent) and Lunder ('000 patent) are drawn toward plant extracts, and related processes, *neither of these references* describes, contemplates, or suggests *specifically* removing substantially all entities having a molecular weight greater than about 10,000 from the extract to produce a composition of water-soluble phytomedicinal compounds resulting from the specific removal of substantially all entities having a molecular weight greater than about 10 kd. Moreover, the Applicants generally exemplify valuable properties of the compositions specifically produced, i.e., **compositions of 0-10 kd water-soluble entities**, using methods of the present invention.

Neither Ishihara nor Lunder teach that their processes contain or define compounds having phytomedicine properties. The mere fact the Applicants employ procedures of extraction paralleling the concentration of catechins in plant water extracts does not in the least define the composition of compounds in Applicants' resulting extracts. **Ishihara and Lunder are concentrating extracts with regard to catechins - nothing else.** The Applicants' procedure focuses on specific removal of greater than 10 kd conjugates under conditions that allow the specific phytomedicinal compounds 0-10kd to remain. The only biological property taught by Lunder or Ishihara is that catechins have antimicrobial activity. The Applicants teach that phytomedicinal compositions specifically produced by the process claimed herein directly control human cell biological responses involved in disease development.

Since none of the cited references describe, teach, contemplate, or suggest the production of plant extracts which have reduced toxicity and increased efficacy by means of thermal aqueous extraction and the specific removal of water-soluble molecular entities greater than about 10 kd to produce a specific composition of water-soluble phytomedicinal compounds between about 0 and about 10 kd in size, the Applicants respectfully submit that the claimed invention cannot be obvious as a matter of law.

The Applicants accordingly respectfully request the Examiner to withdraw the rejections under 35 USC § 103.

The Applicants respectfully acknowledge the Examiner's provisional double patenting rejection and herein agree to prospectively execute a terminal disclaimer to expedite the matter in the event claims are allowed.

The Applicants respectfully submit that claims 1-12 and 14-15 are in condition for allowance. Early action toward this end is courteously solicited. The Examiner is kindly encouraged to telephone the undersigned in order to expedite any detail of the prosecution.

The Commissioner is further authorized to charge any deficiency or credit any overpayment to Deposit Account No. 50-1943.

Respectfully submitted,

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